

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BERNER et al.
APPLICATION No.: 10/769,574
FILED: JANUARY 29, 2004
FOR: **GASTRIC RETENTIVE ORAL DOSAGE FORM WITH
RESTRICTED DRUG RELEASE IN THE LOWER
GASTROINTESTINAL TRACT**

EXAMINER: HOLT, A.
ART UNIT: 1616
CONF. No: 8962

DECLARATION OF JOHN W. SHELL AND JENNY LOUIE-HELM
UNDER 37 C.F.R. § 1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, John W. Shell and Jenny Louie-Helm, declare and affirm as follows:

1. We are co-inventors of the subject matter described and claimed in the above-identified application (herein "the instant application"). The instant application claims the benefit of an application filed October 25, 2001.
2. The claimed subject matter in the instant application relates to a method for delivering an active agent by orally administering to a patient in a fed mode dosage form comprised of a polymer matrix comprised of a hydrophilic polymer, wherein the dosage form swells upon imbibition of water to a size effective to promote gastric retention and maintains its size for an extended period of time before being diminished by erosion.
3. We are named co-inventors, along with Micheline Markey, of U.S. Patent Application Publication No. 2001/0018070, published August 30, 2001

(hereinafter "the Shell publication"). The Shell publication describes a dosage form that swells after oral administration to a size sufficient for gastric retention.

4. The subject matter described in the Shell publication that relates a dosage form comprised of a hydrophilic polymer matrix and an active agent, that swells upon imbibition of water to a size effective to promote gastric retention and maintains its size for an extended period of time before being diminished by erosion was conceived or invented by us, John Shell and Jenny Louie-Helm. Co-inventor Micheline Markey named on the Shell publication contributed to subject matter set forth in the Shell publication that is not the subject of the claims in the instant application.

We declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

May 6, 2009
Date

John W. Shell
John W. Shell

Date

Jenny Louie-Helm

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4. The subject matter described in the Shell publication that relates a dosage form comprised of a hydrophilic polymer matrix and an active agent, that swells upon imbibition of water to a size effective to promote gastric retention and maintains its size for an extended period of time before being diminished by erosion was conceived or invented by us, John Shell and Jenny Louie-Helm. Co-inventor Micheline Markey named on the Shell publication contributed to subject matter set forth in the Shell publication that is not the subject of the claims in the instant application.

We declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date

John W. Shell

06 MAY 09

Date



Jenny Louie-Helm